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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,728	09/20/2000	Lawrence W. Stanton	SCIOS.013A	8743

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/665,728	STANTON ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2003 and 09 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-47* is/are pending in the application.

4a) Of the above claim(s) *40-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *34-47* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 September 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 34-47 are pending in the instant application. Claims 1-8 and 30-33 have been canceled and claims 34-47 have been added as requested by Applicant in the Paper filed Oct. 10, 2003.

Election/Restrictions

2. Applicant's election without traverse of Group I in the Paper filed Feb. 9, 2004 is acknowledged.

Claims 40-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement.

Claims 34-39 are currently under examination.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Method of determining if gene P00210_D09 is differentially expressed in disease states.

Claim Objections

4. Claim 34 is objected to because of the following informalities: it recites "wherein the ***gene*** comprises SEQ ID NO: 2". Genes from mammals typically comprise more DNA sequences, such as introns that are spliced out, than the expressed mRNA. The polynucleotide of

SEQ ID NO: 2 was made from mRNA, which would have the introns spliced out, and would not comprise the other elements present in the gene. It is suggested that "gene" be replaced with "polynucleotide" or "nucleic acid". Appropriate correction is required.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5.1 Claims 34-39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to a method of identifying a gene differentially expressed in a disease state comprising providing a subject, inducing a disease state, and determining the expression pattern of the gene before and after inducing the disease state. A "subject" could include a human subject, and humans are not experimented on in this manner. This rejection could be overcome by including the limitation of a "non-human" subject.

5.2 Claims 34-39 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 34-39 are directed to a method of determining if the gene of SEQ ID NO: 2 is differentially expressed in a disease state, comprising determining the expression level of the gene in a subject, inducing a disease state in the subject, and determining the expression level of the gene after inducing a disease and comparing the levels. However, this method does not have a specific and substantial utility, as determined according to the current Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

The instant specification discloses a rat nucleic acid of SEQ ID NO: 2 encoding the protein of SEQ ID NO: 1, identified as clone P00210_D09. The instant specification discloses that the polypeptide of P00210_D09 is a 275 amino acid protein, and that it is a secreted protein based on the presence of a putative signal sequence (amino acids 1-21), and that the protein has two putative membrane spanning segments from amino acids 35-55 and 123-143. The specification teaches that P00210_D09 encodes a rare message, and that the sequence of P00210_D09 was compared with sequences in the public GenBank, EMBL, DDBJ and GENESEQ databases, and the search revealed no significant homology with sequences present in the searched databases. Clone P00210_D09 was identified using differential gene expression assays, in which the left ventricles of male rats were surgically manipulated to produce a myocardial infarction (MI), tissue was collected at 2, 4, 8, 12 and 16 weeks post-surgery, and used to produce mRNA for microarray analysis. Septum tissue was also obtained from diseased rat hearts as in the same MI model, and mRNA was also produced and analyzed by microarray analysis. From the microarray results, the expression level of the gene corresponding to the clone referred to a P00210_D09 was 2.1-fold higher at the 2 week time point in the rat left ventricle and 1.8-fold higher at the 2 week time point in the septum, which suggests the possible involvement of this gene in the development and/or progress of MI (Fig. 6). The specification teaches that this gene can be screened to obtain more information about the biological function of gene and encoded protein, and that this further information can lead to the designation of this gene or similarly differentially expressed genes or their gene products as potential therapeutic or diagnostic molecules or targets for identifying such molecules (pages 24-25). Though this differential expression after myocardial infarction is scientifically interesting and potentially

useful, the method of using the nucleic acid of SEQ ID NO: 2 does not have any specific and substantial utility, or a well established utility, because any new polynucleotide can be used to determine if it is differentially expressed in a disease state, and thus this utility is not specific. This is a utility that is nonspecific and would apply to every member of a general class of materials, such as expressed genes. While this may be a well-established use of polynucleotides in general, it is not a well-established, specific and substantial utility of the polynucleotide of SEQ ID NO: 2.

Use of clone P00210_D09 to discover its biological function and possible role in disease states is not a specific and substantial utility, and is only further research to discover what the activities and biological significance of the protein and encoding nucleic acid are. At the present time, clone P00210_D09 cannot be used diagnostically or therapeutically, and there is no information provided that suggests that P00210_D09 could be used as a diagnostic before the onset of disease.

The instant claims are drawn to a method of using a polynucleotide encoding a protein which has undetermined function or biological significance to determine if it is differentially expressed in a disease state, and the use of a polynucleotide to discover its potential significance or biological properties does not constitute a specific, substantial utility. It is possible that after further characterization, this polynucleotide or protein might be found to have a patentable utility, such as differential expression in a subject prone to myocardial infarction, which would make it useful as a diagnostic. This further characterization, however, is part of the act of invention, and until it has been undertaken the Applicants' claimed invention is incomplete.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 34-39 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Furthermore, even if the method was enabled, it would only be enabled for mammals, since the polynucleotide of SEQ ID NO: 2 is a rat nucleic acid, so that it would probably hybridize adequately to other mammalian nucleic acids, but not to non-mammalian orthologs.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 34-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 34-39 are indefinite because claim 34 is an indefinite method claim. The preamble of claim 34 encompasses a method for identifying genes, but in the conclusion the method is to determine the expression of one particular gene, that of SEQ ID NO: 2, not to identify genes. Claim 34 should be amended to encompass a method for determining if the gene of SEQ ID NO: 2 is differentially expressed in a disease state.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

Official papers Before Final and After Final filed by RightFax should be directed to (703) 872-9306.

The customer service RightFax number is (703) 872-9305.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Eileen B. O'Hara, Ph.D.

Patent Examiner